

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH  
CENTRAL DIVISION

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NEXMED HOLDINGS, INC.,  
a Delaware corporation

Plaintiff,

vs.

BETA TECHNOLOGIES, INC.,  
a Utah corporation and CHESTER  
HEATH, an individual,

Defendants.

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ORDER and MEMORANDUM  
DECISION

Case No. 2:06-CV-1014 TC

Plaintiff NexMed Holdings, Inc. (“NexMed”) is the owner of United States Patent Number 5,133,352 (the “‘352 Patent”). The ‘352 Patent covers a method for treating the herpes simplex virus by applying electricity to the site of developing lesions. The Defendants, Beta Technologies, Inc. and Chester Heath (collectively, “Beta Tech”), sell a product that NexMed alleges infringes on several claims of the ‘352 Patent. Among Beta Tech’s defenses is that the ‘352 Patent is invalid. Beta Tech has filed motions for summary judgment asserting this defense. Beta Tech also disputes NexMed’s proposed definitions of several terms of the claims of the ‘352 Patent.

The court has determined that construing the disputed claims of the ‘352 Patent would assist in resolving the outstanding summary judgment motions. To this end, the parties submitted briefing and a hearing was held on July 7, 2008. This Order addresses the construction of the disputed claims.

## **BACKGROUND**

Patent '352 originally issued in 1992. In an Ex Parte Reexamination Certificate (the "Certificate") that issued on November 6, 2007, certain claims of the patent were rejected, accepted, or amended. The parties dispute the meaning of certain terms used in Claims 5, 7, 10, and 13 of the '352 Patent as set out in the Certificate. Those claims are set out below, with the disputed terms underlined:

[Claim] 5: In the treatment of the symptoms of Herpes Simplex 1 and 2, the method of inhibiting development of herpetic lesions in the human body upon occurrence of precursor symptoms which comprises:

applying a low DC electrical voltage directly to the body at the site of the precursor symptoms of developing herpes virus lesions at two points spaced apart a distance of one-half inch to one-and-one-half inches;

applying said DC voltage for a very short period of time of less than one minute;

repeating the application of said DC voltage at regular intervals of time of less than two hours over an extended period of time until the precursor symptoms disappear.

[Claim] 7: In the treatment of the symptoms of Herpes Simplex 1 and 2, the method of inhibiting development of herpetic lesions in the human body upon occurrence of precursor symptoms which comprises:

applying a low DC electrical voltage directly to the body at the site of the precursor symptoms of developing herpes virus lesions at two points spaced apart a distance of one-half inch to one-and-one-half inches;

applying said DC voltage for a duration of 3 to 20 seconds at intervals between 45 minutes and 75 minutes;

repeating the application of said DC voltage at regular intervals of time less than two hours over an extended period of time until the precursor symptoms disappears.

[Claim] 10. The method of treating Herpes Simplex 1 and 2 virus infections of the human body which cause lesions to appear on the skin which comprises the steps of:

applying a low DC voltage directly to the body skin at the side of the virus lesions at two points spaced apart a distance of one-half inch to one-and-one-half inches;

applying said DC voltage for a very short time duration of less than one minute;

repeating the application of said DC voltage at regular intervals of less than two hours; and

continuing the periodic application of said DC voltage for at least eight hours or until the lesions heal.

[Claim] 13. The method of treating Herpes Simplex 1 and 2 virus infections of the human body which cause lesions to appear on the skin in accordance with claim 10 which comprises the steps of:

applying a low DC voltage directly to the body skin at the side of the virus lesions at two points spaced apart a distance of three quarters to one-and-one-half inches;

applying said DC voltage for a duration of 3 to 20 seconds at intervals between 45 minutes and 75 minutes.

(Certificate, Claims 5-13, attached as Ex. B to Pl's Claim Construction Br.)

In sum, the parties disagree over the meaning of the terms "treating" or "treatment of" herpes, "inhibiting" herpetic lesions and "low DC voltage" or "low DC electrical voltage."<sup>1</sup>

### **The Parties' Proposed Constructions**

#### **"Treating" or "Treatment" and "Inhibiting"**

For its part, NexMed asserts that "treating" or "inhibiting" do not need construction. NexMed argues that these are preamble terms that simply set out the purpose of the claim terms that follow. On this basis, NexMed asserts that the terms are not limitations and do not need to be construed. In the alternative, NexMed argues that those words have an ordinary meaning that can be determined by looking at the dictionary. Namely, "treating herpes" means "to apply or

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<sup>1</sup>Beta Tech also argues that certain time and spacing limitations in the claims are invalid, but does not expressly offer any proposed construction of them. The court declines to reach the validity of any claims in this Order, whose purpose is claim construction. Moreover, even accepting *arguendo* Beta Tech's implied argument that the time limitations should be construed by reference to the preferred embodiment, the embodiment's narrative states that the "specific duration and time intervals can be adjusted." (Patent '352, column 7 line 27-28.) In other words, the time intervals described in the claims are clear on their face, even when considering the specification.

administer a procedure for relieving or lessening the symptoms of Herpes.” “Inhibiting” herpes lesions means “decreasing or limiting” those lesions.

Beta Tech responds that “treating” and “inhibiting” are indeed limitations, because although they appear in the preamble, they breathe life into the claims. Beta Tech then argues that Patent ‘352’s specification and prosecution history establish a detailed and complex definition of those claims.

**“Low DC Voltage” and “Low DC Electrical Voltage”**

NexMed contends that the phrases “low DC voltage” and “low DC electrical voltage” have an ordinary meaning to a person skilled in the art. According to NexMed, those phrases mean “a voltage that results in a unidirectional current flow that is at most mildly discernable by the user.” NexMed relies on Patent ‘352’s specification to argue that “‘low’ in the context of the patent-in-suit means less than or equal to 30 milliamps.” (Pl’s Claim Construction Br. at 8.) NexMed also points to the patent’s prosecution history to argue that the inventor stated that “low” is “in most cases . . . more like microamps.” (*Id.* at 12.) NexMed refers to the dictionary to assert that “DC” means a unidirectional electrical current. In support of its proposal that the definition include a reference to the discernability of the user, NexMed cites the specification and the prosecution history.

Beta Tech counters that “low DC voltage” and “low DC electrical voltage” mean “9 volts of constant 30 milliamps of current.” In support of limiting the definition to a current flow of exactly 9 volts and 30 milliamps, Beta Tech argues that all the claims are “step-plus-function” in nature or too indefinite, so that their scope so should be limited to the embodiment described in the specification only. Meanwhile, to support its contention that the court should construe the DC current as constant, Beta Tech argues prosecution history estoppel.

### ANALYSIS

Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). “The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). When determining how a person of ordinary skill in the art would understand terms, the terms should be considered “not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” Id. In addition to the claim terms and specification, courts should also refer to the prosecution history where appropriate. See Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed. Cir. 2004).

During the claim construction process, a court must bear in mind that “[w]hen claims are amenable to more than one construction, they should, when reasonably possible, be interpreted to preserve their validity.” Modine Mfg. Co. v. United States Int’l Trade Comm’n, 75 F.3d 1545, 1557 (Fed. Cir. 1996).

#### “Treating” or “Treatment” and “Inhibiting”

The court agrees with NexMed that there is no need to construe the terms “treating” or “treatment” and “inhibiting” used in the preambles of the disputed claims. As explained by the Federal Circuit:

If . . . the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention’s limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). See also Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1288-89 (Fed. Cir. 2008) (“Absent clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim, the preamble ‘generally is not limiting.’”) (citation omitted).

In each of the claims, the terms “treatment of” or “treating” herpes merely state the purpose or intended use of the method described in the claims. The steps described in the claims are not in any way altered even if they do not actually treat herpes. See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375 (Fed. Cir. 2001) (finding that preamble phrase “for reducing hemotologic toxicity” was not a claim limitation because “[t]he steps of the three-hour infusion method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity”). Likewise for the term “inhibiting” herpetic lesions in Claims 10 and 13: the recited steps in those claims do not change based on whether or not they actually inhibit lesions. See id.

In light of the intent of the preambles and Beta Tech’s failure to argue that the inventor relied on the preamble terms in prosecuting the patent, the court finds that there is no need to construe the preamble terms “treating” or “treatment” and “inhibiting” in the disputed claims.

#### **“Low DC Voltage” or “Low DC Electrical Voltage”**

The parties appear to agree that “DC” means “a unidirectional current flow.” This definition is confirmed by reference to a dictionary.<sup>2</sup> See Phillips, 415 F.3d at 1314 (lay judges may refer to dictionaries when the ordinary meaning of a term is readily apparent.) Nor does

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<sup>2</sup>“direct current: An electric current that moves in one direction with constant strength.” Dictionary.com. The American Heritage Science Dictionary. Houghton Mifflin Company. [http://dictionary.reference.com/browse/direct current](http://dictionary.reference.com/browse/direct%20current).

NexMed dispute Beta Tech's assertion that during the prosecution history, the inventor limited the electrical current described in the claims to one that is constant in nature. Further, NexMed and Beta Tech both argue that Patent '352's specification's preferred embodiment, which uses a 9 volt battery to provide a current of at most 30 milliamps, is key to construing the terms "low DC voltage" and "low DC electrical voltage." But the agreement ends there.

On one hand, Beta Tech argues the terms should be construed using a "step-plus-function" analysis under 35 U.S.C. § 112(6). Under such an analysis, Beta Tech contends, the court should limit the electrical current to that described in the specification. Since the only embodiment in the specification describes using a 9 volt battery putting out a maximum of 30 milliamps, the claims should cover only that type of current. Beta Tech further argues that "low" is a relative term left undefined by patent, and unless the court limits the term "low" to an exact amount, the claims will be too indefinite to be valid.

NexMed takes the position that 9 volts and 30 milliamps were, at most, intended as maximum amounts. NexMed contends that the prosecution history shows that the invention was meant to cover microamps, current that is many times weaker than milliamps. In any event, instead of describing any exact amount of current, NexMed maintains, the terms should be defined by discernability to the invention's user. NexMed bases this contention on the specification and prosecution history. NexMed further disputes that the claims are "step-plus-function" claims, or that terms are too indefinite.

The court finds that the claims are not "step-plus-function" in nature. "[W]here a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act." Masco Corp. v. United States, 303 F.3d 1316, 1327 (Fed. Cir. 2002). Here, the claims each describe

steps to be taken, and there are no open-ended functions described in any claim. As such, the court declines to limit the terms to the preferred embodiment's description.

The court, however, finds that some definite value must be associated with the phrases "low DC voltage" or "low DC electrical voltage." NexMed's suggestion that the court should refer to whether an unidentified user notices the electrical current does not fit that bill. On the other hand, Beta Tech's insistence that the terms cannot be defined as a range with a lower limit of zero is unsupported and is clearly an attempt to avoid having the court include a value that covers the allegedly infringing device. Considering the words of the claims, the specification, the prosecution history, and the parties' admissions, the court defines the terms "low DC voltage" and "low DC electrical voltage" as follows: "*a voltage that results in a constant unidirectional flow not to exceed 30 milliamps.*"

SO ORDERED this 15th day of July, 2008.

BY THE COURT:

A handwritten signature in black ink that reads "Tena Campbell". The signature is written in a cursive, flowing style.

TENA CAMPBELL  
Chief District Judge